UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
THIS DOCUMENT RELATES TO:	)	Civil Action No. 01-12257-PBS
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al., Civil Action No. 05-11084-PBS	)	Subcategory No. 06-11337-PBS Hon. Patti B. Saris

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEY DEFENDANTS' MOTION IN LIMINE TO EXCLUDE FROM EVIDENCE THE REPORTS AND TESTIMONY OF STEPHEN W. SCHONDELMEYER

Claiming his testimony constitutes inadmissible "legal" opinion and impermissible opinions on what Dey knew about average wholesale prices (AWPs) and Medicare and Medicaid drug reimbursement, Dey seeks to exclude the testimony of Stephen W. Schondelmeyer, Pharm.D, Ph.D, a nationally and internationally respected expert in pharmaceutical policy and economics. Dey's motion should be denied. Dey misconstrues the nature of Dr. Schondelmeyer's opinions in critical respects, misstates the law governing the admissibility of expert testimony, and simply misses the mark as to the foundation for Dr. Schondelmeyer's opinions about how Medicare and Medicaid operate.[1]

Dr. Schondelmeyer's initial and rebuttal reports focus on the structural framework of the Medicare and Medicaid programs (including the joint federal-state nature of the Medicaid program), and the programs' reliance upon drug prices from Dey and other manufacturers in

[1] The Court's decision regarding whether to bifurcate the Medicare claims for trial will impact the scope of any testimony from Dr. Schondelmeyer. The bulk of Dey's motion addresses Dr. Schondelmeyer's testimony regarding the Medicaid program.

determining reimbursement amounts. Dr. Schondelmeyer also addresses differences between Medicare and Medicaid reimbursement methods, as well as differences among various state Medicaid programs. He appropriately opines about the information that is publicly available to government regulators (or not) about drug prices, the countervailing considerations that attend different choices of reimbursement methodologies, and the need for reliable and accurate prices to make informed decisions about reimbursement.

Dey's motion to exclude this testimony is directed at three broad categories of opinions: supposed legal opinions; testimony about what Dey knew or intended; and testimony about how reported and published drug prices are utilized in the operation of the Medicare and Medicaid programs. Dey's motion fails on all three points. First, contrary to Dey's assertions, Dr. Schondelmeyer does not offer legal opinions. Second, with respect to what Dey knew regarding government reimbursement and what it intended to achieve by reporting inflated prices, such testimony is an appropriate subject of expert testimony and well within Dr. Schondelmeyer's expertise. Finally, Dr. Schondelmeyer is well-qualified to explain how the Medicare and Medicaid programs as a whole actually used Dey's reported prices, and there is simply no basis to exclude this fundamental testimony.[2]

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[2] Dey's characterization of Dr. Schondelmeyer as "plaintiffs' in-house expert" is inaccurate and irrelevant. First, Dr. Schondelmeyer has performed work for many organizations, including HCFA/CMS, the U.S. Food and Drug Administration, pharmaceutical firms, various state agencies and assorted foreign governments. *See generally* Expert Report of Dr. Schondelmeyer ("Rep."), ¶¶ 6-8. In addition, Dr. Schondelmeyer has frequently testified *against* the Department of Health and Human Services (HHS) or state Medicaid agencies. Various defense experts in other AWP cases have cited studies performed by Dr. Schondelmeyer or the research institute which he founded and ran for many years, because it is virtually impossible to research drug payment policies and trends in drug prices without utilizing his work. Even Dey's primary expert admits Dr. Schondelmeyer is "well respected" in the fields of pharmaceutical economics and health care policy. Deposition of David Bradford, 8-27-2009, at 24:24-25:17, in *State of Texas ex rel. Ven-a-Care of the Florida Keys, Inc. v. Sandoz, Inc., et al.* (Dist. Ct. Travis Cty, Tex.). In any event, the First Circuit has held that even employees of parties, which Dr. Schondelmeyer is most assuredly not, may testify as experts. *See Den norske Bank AS v. First Nat'l Bank*, 75 F.3d 49, 58 (1st Cir. 1996); *Collazo-Santiago v. Toyota Motor Corp.*, 149 F.3d 23, 28 (1st Cir. 1998).

ARGUMENT

I. Dr. Schondelmeyer Will Not Offer Legal Opinions

Courts have recognized that experts may need to refer to regulations in the course of testimony and that such references do not equate to legal opinions. In many instances, courts have admitted general background testimony despite recognition that there is some overlap or entanglement between discussing regulatory compliance and pronouncing applicable law. In *Darling v. IndyMac Bank, F.S.B*, 2007 WL 4276903, * 5 (D. Me. Dec. 3 2007), for example, the court addressed a challenge to the admissibility of expert testimony that certain conduct violated the Truth in Lending Act (TILA). Recognizing that "an expert might need to speak in terms of the TILA's regulatory framework in order to discuss regulatory compliance," the court stated that "for testimony about noncompliance to have meaning there is a need to convey to the fact finder that there exists a regulatory framework that mandates compliance." *Id.* The court also noted that the "most appropriate" way to handle such testimony is "to provide the jury with preliminary instructions concerning the regulatory framework" and "require the expert to couch his compliance testimony in terms of the Court's instructions on the law, rather than in terms of his private characterizations." *Id.*; *see also Powell v. Nunley*, 2010 U.S. Dist. LEXIS 26596, *5-6 (W.D. Okla. Mar. 22, 2010) (admitting expert testimony about police practice and noting that the "fact that police practices may be motivated in part by the need to comply with legal standards … does not mean that opinions as to those practices are necessarily improper legal opinions"). Courts regularly admit such testimony where it would help the fact-finder understand a complex or unfamiliar regulatory scheme. *See, e.g.*, *Reece v. Astrazeneca Pharms., LP*, 500 F. Supp. 2d 736, 744 (S.D. Ohio 2007) (admitting expert testimony on "the regulations governing the approval, labeling, advertising and marketing of pharmaceutical and medical

products; the processes by which the FDA determines the efficacy and safety of new drugs and new drug applications; the issues the FDA considers in the development of product labeling and marketing information; and a manufacturer's responsibility within this system").[3]

Dr. Schondelmeyer's testimony describes, among other things, the channels of drug distribution and the sources of payment within the pharmaceutical market, including public third party insurers such as Medicare and Medicaid. Rep. at ¶¶ 36-40. In particular, Dr. Schondelmeyer explains the role of drug manufacturers' price reporting and the commercial pricing compendia in determining reimbursement. *Id.* at ¶ 76 (explaining that Medicare and Medicaid need to rely upon readily available and current market information such as that supplied by drug manufacturers and drug price publishing services because of the large number of claims that make individual transaction prices impractical and inefficient to determine on a claim by claim basis). As background to these opinions, Dr. Schondelmeyer provides an overview of pharmaceutical pricing, including the elements of specific drug pricing terms such as "estimated acquisition cost." *Id.* at ¶¶ 45-50. Dr. Schondelmeyer does not purport to give legal opinions; rather, he draws on his training and experience in health care policy to explain the context and history of the regulations in question. Deposition ("Dep.") of Stephen W. Schondelmeyer, Feb. 25, 2009, May 21-22, 2009, at 200:22-202:5; 1217:17-1218:3; 1346:12-22; 1539:19-1542:2 (Exhibit 1).

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[3] *See also Flanagan v. Altria Group, Inc.*, 423 F. Supp. 2d 697, 700-702 (E.D. Mich. 2005) (accepting opinion from expert "who, primarily through his experience with the FTC's Bureau of Economics, has acquired specialized knowledge about a complex issue – the FTC's regulation of cigarette advertising and promotion. His understanding of this issue has been helpful to the Court in explaining the significance of various FTC actions (and would potentially be helpful to a jury as well)"); *Lillebo v. Zimmer, Inc.*, No. 03-2919 (JRT/FLN), 2005 WL 388598, at *5 (D. Minn. Feb.16, 2005) (allowing expert "to testify to the general nature of the approval and regulatory process, the FDA's general expectations with respect to testing and marketing of new products, [defendant's] actions in that respect, and [expert's] opinion as to whether those actions were reasonable or appropriate," but not permitting her to detail specific FDCA and FDA standards).

In Dey's view, Dr. Schondelmeyer "repeatedly opines" that the estimated acquisition cost regulation, 42 C.F.R. § 447.301, required drug manufacturers to report drug prices that are "generally and currently paid by providers." Dey Memorandum ("Mem.") at 4. An expert's reference to the exact language of a regulation is not, however, a legal opinion. Here, Dr. Schondelmeyer correctly notes that the EAC regulation was "defined as 'the price generally and currently paid by providers for a particular drug in the package size more frequently purchased by providers." Rep., ¶ 54. This is consistent with how this Court previously described it. *See, e.g., Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 132 (D. Mass. 2008) ("Under federal Medicaid regulations, a state Medicaid program's payments for a drug may not exceed the 'estimated acquisition cost' of the drug . . . where the 'estimated acquisition cost" (EAC) is defined as "the agency's best estimate of the price generally and currently paid by providers . . . .'").[4]

In addition, Dey's argument that the federal regulations did not require that state Medicaid programs use EAC as the central basis of their reimbursement systems after 1987 does not provide a basis to exclude Dr. Schondelmeyer's testimony. Fed. R. Evid. 702, Notes of Advisory Committee on 2000 Amendments ("The emphasis in the amendment on 'sufficient facts or data' is not intended to authorize a trial court to exclude an expert's testimony on the ground that the court believes one version of the facts and not the other.") In any event, Dey ignores that every state did, in fact, continue to set reimbursement according to EAC, as Dr. Schondelmeyer notes. Rep., ¶¶ 120-122, 149-153. Moreover, Dey's theory that the use of the term "in the aggregate" in the 1987 regulation displaced the central element of cost-based

[4] Any dispute that Dey has with Dr. Schondelmeyer's understanding of the applicable regulations is really just an argument that he is wrong – not that he is unqualified or lacks a basis for his opinions. Disagreement with the well-founded views of a qualified expert is not a basis for excluding the expert.

reimbursement, overturned the earlier and subsequently repeated directive to consider drug ingredient cost and dispensing fees separately, and somehow authorized a system of cross-subsidization, is not supported by any reasonable reading of the 1987 regulation, and does not address the permissible bounds of manufacturer price reporting. Thus, even if Dey persuades this Court of its interpretation of the 1987 regulation, an interpretation Plaintiffs dispute, it is of no significance because the states in fact used EAC and there is no evidence that any state attempted to utilize the "in the aggregate" concept. Certainly, there is nothing in the record to demonstrate that state Medicaid programs used this regulation to justify adoption of whatever prices a manufacturer chose to report as the basis of a drug reimbursement program.[5]

Dey also repeatedly claims that Dr. Schondelmeyer opines regarding a legal duty imposed on manufacturers to report prices to the government. *See* Dey Mem. at 1, 2, 3, 4, 5 & 6. Dr. Schondelmeyer, however, is fully aware that there was no outright requirement for any manufacturer to report AWPs to the government. Instead, he generally refers to the practical realities that cause manufacturers to report prices to the compendia – realities that Dey's own expert similarly acknowledges. Rep. at ¶¶ 127-128; Report of W. David Bradford, March 6, 2009, at ¶ 88.

It is clear in this case that the Court will have to issue preliminary jury instructions describing the law with respect to pharmaceutical reimbursement for both the Medicare and Medicaid programs, the most obvious topics being the meaning of AWP and EAC. Any concern

[5] Dey's support for this theory appears limited to Robert Helms, a former HCFA employee whom defendants retained as an expert, and whose primary proposals for changes to drug reimbursement policy were rejected by Congress. The United States intends to move to exclude Mr. Helms's testimony, since he does offer legal opinions, and will elaborate in more detail in that motion regarding the 1987 regulation. Notably, even Mr. Helms does not opine that the 1987 regulation addressed and approved of the manufacturer price-reporting practices at issue.

that the jury may view Dr. Schondelmeyer as offering legal opinions is attenuated by the fact that his opinions recite, rather than interpret, the applicable regulations, and do so in a manner consistent with prior holdings of this Court. *Cf. IndyMac Bank, F.S.B*, 2007 WL 4276903, *5.

II. Dr. Schondelmeyer Is Qualified to Testify as to Dey's Knowledge about Government Reimbursement Policies

Experts are routinely permitted to testify regarding the knowledge of defendants on particular topics. This is especially true where the subject matter is complex and technical. The district court in *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 2d 722, 726-727 (E.D.N.C. 2007), for example, observed that:

> As is clear from even a cursory review of the evidence in this matter, the facts surrounding the claims at issue are highly complex and technical. The average layperson has no experience pertaining to what is or is not common knowledge within the telecommunications field. The same holds true for the Jeffay, Stout and Utas reports, which all offer opinion within their relative areas of expertise as to what defendant, or its employees were aware of based on documents and evidence reviewed.

Id.; *see also In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, 643 F. Supp. 2d 482, 497-499 (S.D.N.Y. 2009) (permissible for expert to testify about availability of information to members of industry regarding certain problems with products). In *Methyl Tertiary Butyl*, the court specifically noted that "public statements, internal and external statements of trade groups of which Exxon was a member, and communications produced or received by Exxon" are exactly the types of documents that can inform an expert of what was generally known. *Id*. at 497.

Dey seeks to exclude Dr. Schondelmeyer's testimony about what manufacturers knew, or what Dey is presumed to have known. As set forth above, such testimony is an appropriate subject of expert testimony given the complexity of pharmaceutical reimbursement and pricing. Such testimony is also well within Dr. Schondelmeyer's expertise. He has worked in the area of pharmaceutical reimbursement, particularly within government programs, for over 30 years and

his conclusions about what manufacturers in general, or Dey in particular, knew are based on that experience, his work with various federal and state drug programs, his awareness of the common availability of the National Pharmaceutical Council's publication "Pharmaceutical Benefits Under State Medical Assistance Programs" (also referred to as the "NPC Medicaid Book"), and his review of Dey documents showing the company's awareness of reimbursement methodologies. *See e.g.*, Rep. at ¶¶ 13, 20, 54, 90-103. Plainly, this type of testimony is admissible when Dey has argued that even if its reported prices were false, its conduct was not "knowing" within the meaning of the False Claims Act. *See* Dey's Memorandum of Law in Support of Their Motion for Partial Summary Judgment at 12-14 (Dkt. No. 6194, Subdkt. No. 249).

Dey's underlying criticism that Dr. Schondelmeyer only reviewed a small percentage of the huge evidentiary record in this case, and that the documents were selected by plaintiffs' counsel, is similarly unavailing. Dr. Schondelmeyer did review internal Dey documents sufficient to formulate his opinions in this case. *See* Rep., ¶¶ 90-103 (detailing Dey documents and testimony). Nonetheless, Dr. Schondelmeyer's opinions are based generally upon his extensive experience in the pharmaceutical industry and not dependent upon a detailed review of Dey's pricing or marketing practices. This review, coupled with Dr. Schondelmeyer's decades of experience, easily qualifies him to offer expert opinions in this case. *See United States v. Oussama Abdullah Kassir*, 2009 U.S. Dist. LEXIS 28837, 16-18 (S.D.N.Y. Apr. 2, 2009) (admitting testimony where expert gathered "multiple sources of information, including original and secondary sources" and cross-checked and juxtaposed new information to check conclusions). The *Kassir* court rejected a challenge to the testimony based on accusations of cherry-picking of information and an inability to scientifically test the sufficiency of the

information on which the conclusions were based. *Id*. The court deemed cross examination as the appropriate means to address the concerns that were raised. *Id*.

In any event, if Dey wishes to challenge Dr. Schondelmeyer's report and testimony by arguing that his review was too limited, Dey must point out material information that he failed to take into account that would likely have changed his conclusions. *See, e.g., In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 531 (6th Cir. 2008) (defendants identified questionable data relied on by expert); *Watkins v. Vestil Mfg. Corp.*, 2010 U.S. Dist. LEXIS 19837 (N.D. Ga. Mar. 5, 2010) (defendant took issue with the numbers and figures used by plaintiffs' expert); *Ellis v. Pa. Higher Educ. Assistance Agency*, 2008 U.S. Dist. LEXIS 112150 at * 8 (C.D. Cal. Oct. 3, 2008) ("On cross-examination, Ellis is free to test the extent to which Ulzheimer's opinion would have been more complete or more accurate if he had reviewed further facts."). Dey cannot point to such information, but even if it could, the challenge would only go to the weight of Dr. Schondelmeyer's opinions, not their admissibility. *Microfinancial, Inc. v. Premier Holidays Int'l, Inc.*, 385 F.3d 72, 81 (1st Cir. 2004); *see also Spine v. Biedermann Motech GMBH*, 2010 WL 535013, at *27 (D.D.C. Feb. 16, 2010) (expert's failure to review certain documents did not render his opinion unreliable under Fed. R. Evid. 702); *Nova Consulting Group, Inc. v. Eng'g Consulting Servs.*, 290 Fed. Appx. 727, 733 (5th Cir. 2008) ("[I]t is not the role of the trial court to evaluate the correctness of facts underlying one expert's testimony.") The proper response to Dey's criticism is cross-examination of Dr. Schondelmeyer or presentation of contrary opinion, not exclusion of his testimony.

III. Dr. Schondelmeyer Should be Permitted to Testify Regarding How the Medicare and Medicaid Programs Used Dey's Reported Prices and the Negative Impact of Inaccurate Prices

Based on his knowledge of the operations of Medicare and the state Medicaid programs (some in great detail and others more generally),[6] Dr. Schondelmeyer opines that Dey's inflated prices resulted in Medicare and Medicaid paying more for drugs overall than they would have if more accurate prices had been reported. Rep. at ¶¶ 23-24. Dr. Schondelmeyer concluded more specifically that more accurate prices by Dey would only sometimes have led to lower payments by Medicare, since payment there was based on a median price. *Id.* at ¶¶ 19, 23-24.

The type of background testimony given by Dr. Schondelmeyer on this topic has been widely accepted by courts, particularly with regard to a complex system or organization that is beyond a normal juror's familiarity. *See generally Rooney v. Sprague Energy Corp.*, 519 F. Supp. 2d 110, 126 (D. Me. 2007) (permitting expert testimony from vocational expert because it will assist the jury to understand the complex nature of the business operation); *Corey Airport Servs. v City of Atlanta*, 632 F. Supp. 2d 1246 (N.D. Ga. 2008) (expert witness in competitive bidding could explain bidding process, which was not matter within common understanding of lay person, thus allowing trier of fact to determine whether company was unlawfully disadvantaged during that process).

Contrary to Dey's suggestion, Dr. Schondelmeyer does not testify with regard to legal causation under the FCA. Dr. Schondelmeyer's testimony instead explains how reported and published prices are used in the operation of the Medicare and Medicaid programs. Thus, he

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[6] Dr. Schondelmeyer did an in-depth study of the Texas Medicaid drug program, for example, *see Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Cost: Final Report* (CMS Contract #500-00-049, Task Order 1, September 26, 2005, Marian V. Wrobel, Stephen W. Schondelmeyer, Shuchita Agarwal, and Janice Cooper), and has worked with, among others, Kentucky, South Dakota, Minnesota, Massachusetts and the Western Medicaid Pharmacy Administrators Association.

describes how the pricing compendia work (a subject he knows well from 10 years as a consultant to MediSpan and his extensive use of the compendia throughout his career) and why government programs rely on the compendia to receive current and comprehensive price data for the tens of thousands of covered NDCs. Rep. at ¶¶ 19, 23-24, 71-78. He addresses the common EAC methodologies of various state Medicaid programs, as well as the existence of alternative reimbursement criteria and other price points. In Medicare, he explains the J-code system and its use of median AWPs. *Id.* at ¶¶ 24, 171, 179-183. This is the factual underpinning of how the reporting of inflated prices leads to the payment of inflated reimbursement. Notably, this Court has already held that manufacturers' reporting of false prices caused the submission of false claims by providers. *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d at 145 ("although the manufacturers do not themselves submit claims to the Commonwealth, and the claims do not themselves contain WACs or AWPs, the claims here were 'predicated on an underlying fraudulent pricing scheme.'"); *California ex rel. Ven-A-Care of the Fla. Keys., Inc. v. Abbott Labs., Inc.* (*In re Pharm. Indus. Average Wholesale Price Litig.)*, 478 F. Supp. 2d 164, 173 (D. Mass. 2007) (same).

Dey contends that Dr. Schondelmeyer's opinion should be excluded as speculative. Dey Mem. at 17-18. Dey's point here is simply rehashing arguments aimed at Dr. Duggan, plaintiffs' damages expert, regarding his refusal to speculate about secondary effects if Dey had reported accurate prices to the compendia, rather than the inflated prices Dey actually reported. The United States has opposed Dey's motion to exclude the testimony and conclusions of Dr. Duggan, and similarly opposed Dey's related motion for summary judgment. Because these subjects have already been the focus of extensive briefing and argument, this memorandum will address the arguments only as they apply to Dr. Schondelmeyer.

Because Dr. Schondelmeyer is describing the existing reimbursement methodologies during the relevant time period, and the way in which reported and published prices were used in those systems, he did not address hypothetical changes that may have come about had some element of the system been different. Based on his extensive experience working with government programs, his understanding of the policy objectives underlying the drug reimbursement programs, and his knowledge of how Dey's reported prices were utilized operationally by the programs, he concluded that "[t]he ability of state Medicaid programs to implement their chosen policy objectives and to manage resources efficiently is negatively impacted by the provision of inflated price information by drug manufacturers, including Roxane and Dey." Rep. at ¶ 115. Especially in light of Dey's argument that its reporting of inflated list prices was sanctioned by the government in furtherance of policy objectives, Plaintiffs should be permitted to offer testimony explaining why government programs relied on reported prices, and their need for honest prices to make informed decisions about reimbursement. Dey's effort to distort Dr. Schondelmeyer's opinions into damages opinions, and then to attack those opinions for failure to have a quantitative analysis behind them, must be rejected.

CONCLUSION

For the reasons stated above, Dey's motion should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above document to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

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Dated: April 21, 2010